

## United States Patent and Trademark Office



| APPLICATION NO.                                     | F          | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |
|---|------------|-------------|----------------------|-------------------------|------------------|
| 10/812,544  | 03/29/2004 |             | Claudio Bucolo       | P03314                  | 3426             |
| 23702   | 7590       | 09/08/2006  |                      | EXAM                    | INER             |
| Bausch & I  | Lomb Inc   | corporated  | HENRY, MICHAEL C     |                         |                  |
| One Bausch & Lomb Place<br>Rochester, NY 14604-2701 |            |             | ART UNIT             | PAPER NUMBER            |                  |
|   |            |             |                      | 1623                    |                  |
|   |            |             |                      | DATE MAILED: 09/08/2006 |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

| -  | Application No.   | Applicant(s)   |
|--|---|--|
|  | 10/812,544  | BUCOLO ET AL.  |
| Office Action Summary  | Examiner  | Art Unit   |
|  | Michael C. Henry  | 1623   |
| The MAILING DATE of this communication appeared for Reply  | pears on the cover sheet w  | vith the correspondence address  |
| A SHORTENED STATUTORY PERIOD FOR REPI WHICHEVER IS LONGER, FROM THE MAILING I  - Extensions of time may be available under the provisions of 37 CFR 1 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period  - Failure to reply within the set or extended period for reply will, by statu Any reply received by the Office later than three months after the maili earned patent term adjustment. See 37 CFR 1.704(b). | DATE OF THIS COMMUN.  136(a). In no event, however, may and will apply and will expire SIX (6) MO te, cause the application to become A | ICATION. I reply be timely filed INTHS from the mailing date of this communication. ABANDONED (35 U.S.C. § 133). |
| Status   |   |  |
| 1) Responsive to communication(s) filed on  2a) This action is <b>FINAL</b> . 2b) The This action for allowed closed in accordance with the practice under   | is action is non-final.<br>ance except for formal ma  |  |
| Disposition of Claims  |   |  |
| 4) Claim(s) 1-68 is/are pending in the application 4a) Of the above claim(s) is/are withdra 5) Claim(s) is/are allowed. 6) Claim(s) is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) 1-68 are subject to restriction and/or  | awn from consideration.   |  |
| Application Papers   |   |  |
| <ul> <li>9) The specification is objected to by the Examin</li> <li>10) The drawing(s) filed on is/are: a) ac</li> <li>Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct</li> <li>11) The oath or declaration is objected to by the Examin</li> </ul>   | cepted or b) objected to<br>e drawing(s) be held in abeya<br>ction is required if the drawing   | nnce. See 37 CFR 1.85(a).<br>g(s) is objected to. See 37 CFR 1.121(d).   |
| Priority under 35 U.S.C. § 119   |   |  |
| 12) Acknowledgment is made of a claim for foreig a) All b) Some * c) None of:  1. Certified copies of the priority documer 2. Certified copies of the priority documer 3. Copies of the certified copies of the priority documer application from the International Burea * See the attached detailed Office action for a lis  | nts have been received.  Its have been received in a point documents have been au (PCT Rule 17.2(a)).                                   | Application No n received in this National Stage   |
| Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO/SB/08)  Paper No(s)/Mail Date   | Paper No  | Summary (PTO-413)<br>(s)/Mail Date<br>Informal Patent Application<br>  |

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## **DETAILED ACTION**

## Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-12, 40-53 drawn to a viscoelastic composition comprising water, a minimum of about 0.0 1% w/v and a maximum of about 10%w/v of hyaluronic acid or a salt thereof and a minimum of about 0.01%w/v and a maximum of about 10%w/v of hydroxpropylmethylcellulose ......, classified in class 514 subclass 54, 57.
- II. Claims 13-25 drawn to a method of temporarily maintaining the space in a cavity in human tissue ......, classified in class 514, subclass 54, 57.
- III. Claims 26-39, drawn to a method of protecting tissue from trauma during a surgical procedure, .......... classified in class 514, subclass 54, 57.
- IV. Claims 54-68, drawn to a method of replacing a natural lens from an eye,.......... classified in class 514, subclass 54, 57.
- 1. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the process for using the product as claimed can be practiced with another materially different product. For example, the process for using the product as claimed can be practiced with a viscoelastic composition comprising an alginate.

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- 2. Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the process for using the product as claimed can be practiced with another materially different product. For example, the process for using the product as claimed can be practiced with a viscoelastic composition comprising an alginate.
- 3. Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the process for using the product as claimed can be practiced with another materially different product. For example, the process for using the product as claimed can be practiced with a viscoelastic composition comprising an alginate.
- 4. Inventions II –IV are all unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects.
- 4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and the burden to search, restriction for examination purposes as indicated is proper.

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5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

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## Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8.30am-5pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael C. Henry

Shaojia Anna Jiang, Ph.D. Supervisory Patent Examiner

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September 5, 2006.